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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/822,037

04/08/2004

Mark C. Bates

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35023

7590

09/03/2008

Mitchell P. Brook

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EXAMINER

BOUCHELLE, LAURA A

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

09/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/822,037	Applicant(s) BATES, MARK C.	
	Examiner LAURA A. BOUCHELLE	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/16/08 has been entered.

Claim Rejections - 35 USC § 102

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 18-31, 35-56, 59, 60 are rejected under 35 U.S.C. 102(b) as being anticipated by Humes (US 5911704). Humes discloses an implantable device and method comprising the steps of providing an apparatus having an anchor 20 expandable from a delivery configuration to a deployed configuration, and a material 10 adapted to elute a bioactive substance, disposing the anchor in the delivery position, advancing the distal end of a delivery sheath to the delivery site, expanding the anchor to engage the interior wall of a vessel, eluting a bioactive substance, and removing the anchor (Col. 16, line 15 – col. 17, line 20). The eluting material may be filaments, which are elongated members adapted for multiple turns. As can be seen in Fig. 6B, the eluting material 10 may comprise two capsules that allow blood to flow therebetween. This is interpreted to meet the claim limitation of eluting material into the blood flowing therethrough.

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3. Humes discloses that the anchor 20 comprises a head 26, barbed filaments 22 biased radially outwardly attached at one end to the head. The anchor comprises an interlocking receptacle for receiving an interlocking element 40 of the capsule 10. See Fig. 6A. The reservoir is an osmotic pump (Col. 9, lines 37-42). The reservoir comprises a biocompatible polymeric semi-permeable membrane defining pores of size sufficient to permit diffusion of preselected drug therethrough over a preselected period of time (Col. 10, lines 16-24, Col. 8, lines 19-22). The drug may be a coagulation factor (Col. 2, lines 20-25).

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 32-33, 57, 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Humes in view of Leong (WO 95/2618). Claims 32, 33 differ from Humes in calling for the eluting material to include a spongy material or a foam. Leong teaches the use of foam to elute drugs after implantation into the body for long term, non-invasive delivery of the drug to a specific area. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Humes to include a drug eluting foam as taught by Leong to provide long term drug delivery to a specific area within the body.

6. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Humes in view of Leong. Claim 34 differs from the teachings above in calling for the spongy member to be steel wool. At the time the invention was made, it would have been an obvious matter of design choice to form the drug eluting member of steel wool. Applicant has not disclosed that having steel wool serves any advantage or particular purpose or solves a stated problem. Furthermore,

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one of ordinary skill would expect Humes and applicant's invention to perform equally well with either a pellet, filaments, foam or steel wool because each are known drug eluting substances. Therefore, it would have been prima facie obvious to modify the device of Humes in view of Leong to obtain the invention as specified in claim 34 because such a modification would have been considered a mere design consideration which fails to patentably distinguish over the prior art.

Response to Arguments

7. Applicant's arguments filed 6/16/08 have been fully considered but they are not persuasive. Applicant argues that there is no motivation to combine the teachings of Leong with Humes. The examiner disagrees. Humes teaches that the capsule be formed of a permeable membrane to allow molecules to elute out of the capsule. Leong teaches a foam loaded with nutrients and/or drugs that elute from the foam. The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, both devices are concerned with eluting a material into the blood stream through a porous material and Leong teaches that the porous material may be a foam.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA A. BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Laura A Bouchelle
Examiner
Art Unit 3763

/L. A. B./
Examiner, Art Unit 3763